SNI

Standar Nasional Indonesia

SNI ISO/TS 17665-3:2017

Sterilisasi produk pelayanan kesehatan - Uap panas (*Moist heat*) - Bagian 3: Pedoman penentuan peralatan kesehatan untuk produk sejenis dan kategori proses dengan sterilisasi uap

(ISO/TS 17665-3:2013, IDT, Eng)

ICS 11.080.01

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Diterbitkan di Jakarta

Daftar isi

Prakata

Standar Nasional Indonesia (SNI) ISO/TS 17665-3:2017, dengan judul *Sterilisasi produk pelayanan kesehatan – Uap panas (Moist heat) – Bagian 3: Pedoman penentuan peralatan kesehatan untuk produk sejenis dan kategori proses dengan sterilisasi uap,* merupakan adopsi identik dari ISO/TS 17765-3:2013, *Sterilization of health care products - Moist heat - Part 3: Guidance on the designation of a medical device to a product family and processing category for steam sterilization,* dengan metode *republikasi – reprint.*

Standar ini disusun oleh Komite Teknis 11-13 *Sterilisasi Produk Pelayanan Kesehatan*. Standar ini telah dibahas dalam rapat teknis dan terakhir disepakati dalam rapat konsensus di Jakarta pada tanggal 14 Maret 2017. Konsensus ini dihadiri oleh para pemangku kepentingan (stakeholder) terkait, yaitu perwakilan dari produsen, konsumen, pakar dan pemerintah.

Standar ini telah melalui tahap jajak pendapat pada tanggal 10 September 2017 sampai dengan 10 Oktober 2017 , dengan hasil akhir disetujui menjadi SNI.

Untuk tujuan penggunaan standar ini, istilah "*this Technical Specification*" diganti menjadi "*this Standard*".

Untuk menghindari kesalahan dalam penggunaan dokumen dimaksud, disarankan bagi pengguna standar untuk menggunakan dokumen SNI yang dicetak dengan tinta berwarna

Perlu diperhatikan bahwa kemungkinan beberapa unsur dari dokumen standar ini dapat berupa hak paten. Badan Standardisasi Nasional tidak bertanggungjawab untuk pengidentifikasian salah satu atau seluruh hak paten yang ada.

Apabila pengguna menemukan keraguan dalam standar ini maka disarankan untuk melihat standar aslinya yaitu ISO/TS 17665-3:2013 (E) dan/atau dokumen terkait lain yang menyertainya.

Pendahuluan

The guidance given in this Standard is not intended as a checklist for assessing compliance with ISO 17665-1. This guidance is intended to assist in obtaining a uniform understanding and implementation of ISO 17665-1 by providing explanations and acceptable methods for achieving compliance with specified requirements. It highlights important aspects and provides examples. Methods other than those given in this guidance may be used. However, the use of alternative methods has to be demonstrated to be effective in achieving compliance with ISO 17665-1.

The main body of this document is applicable to all settings where moist heat sterilization is carried out. The annexes to this guidance document also specify detailed means of implementing the requirements of ISO 17665-1 and represent current best practices.

The numbering of the clauses in the main body of this Standard corresponds to that in ISO 17665-1.

Medical devices reprocessed in health care facilities include a wide variety of product with varying levels of bioburden. Appropriate and thorough cleaning and, where necessary for safe handling, decontamination processes are essential prior to presenting product for sterilization. Mixed product loads are common in healthcare facilities with throughput volumes dictated by historical and predicted demand for sterile product.

Health care facilities do not normally specify sterilization processes for any individual medical device. Also, it is impractical for health care facilities to determine bioburden on a medical device. It is important that specified instruments be disassembled before decontamination and thoroughly inspected after completion of the sterilization process. Reassembly and assessment of functionality are also needed. Therefore, the medical device manufacturer's instructions (see ISO 17664[23]) should be followed for all aspects of cleaning, disinfection, packaging and sterilization. Many devices can be fully immersed and can be washed and disinfected in automated equipment (see ISO 15883[19-22]). For devices that cannot be fully immersed and that cannot tolerate thermal decontamination, alternative methods of disinfection should be used to ensure safe handling. Such procedures and policies should be in place to ensure that medical devices undergo appropriate reprocessing. Particular attention needs to be paid to the drying and storage of sterile medical devices. Requirements for packaging of medical devices are covered in ISO 11607-1[8] and ISO 11607-2[9].

If multiple sterilization cycles can lead to degradation and limit the useful life of a medical device, the manufacturer will specify the number of reprocessing cycles that can normally be tolerated.

When selecting a medical device, priority should be given to properties such as ease of cleaning and disassembly.

Additional guidance specific to health care is offered in Annex D of this Standard.

Sterilisasi produk pelayanan kesehatan – Uap panas (Moist heat) – Bagian 3: Pedoman penentuan peralatan kesehatan untuk produk sejenis dan kategori proses dengan sterilisasi uap

1 Scope

This part of ISO 17665 provides guidance about the attributes of a medical device to be considered by the user when assigning a medical device to a product family for the purpose of identifying and aligning it to a processing category for a specific moist heat sterilization process.

NOTE While this part of ISO 17665 is applicable to health care facilities, it may be used by a manufacturer of a sterile medical device and/or whenever information on reprocessing is required (see ISO 17664).

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 17665 1:2006, Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 17665-1 and the following apply.

3.1
master product
medical device or procedure set used to represent the most difficult to sterilize item in a product family or processing category

3.2
processing category
collection of different products or product families that can be sterilized together

3.3
steam penetration resistance
challenge to a sterilization process from a medical device, including any sterile barrier/packaging system that may delay attainment of the process parameters for moist heat sterilization on all parts of the medical device

3.4
user
responsible body, which can be an individual or group, accountable for ensuring products are sterilized and suitable for intended use

4 Classification

Each medical device, whether new or modified, should be classified using the general attributes listed in Table 1. Specific characteristics of a medical device should, as applicable, be identified from the subclauses detailed in 4.2.

NOTE 1 Requirements for information to be provided by the manufacturer for the reprocessing of resterilizable medical devices are given in ISO 17664.

If a collection of medical devices are to be contained in a sterile barrier system and/or packaging system e.g. a procedure set, the challenge to the sterilization process from each medical device should be rated relative to the other medical devices as described in this part of ISO 17665. The product family assigned to this collection should be determined by the medical device which presents the greatest challenge to the sterilization process and the sterile barrier system and/or packaging system used. This product family will enable an appropriate processing category and sterilization process to be selected. The combination of the device with the highest rating and the chosen sterilization process should be subject to qualification in accordance with ISO 17665 1.

NOTE 2 Requirements and guidance for sterile barrier systems and packaging systems may be found in ISO 11607 (all parts) and EN 868 (all parts).

Some combinations of physical characteristics, such as those specified in Table 1, may cause an unpredictable adverse change to the steam penetration resistance as illustrated in Table 6. This can lead to an underestimation of the difficulty to sterilize (see Clause 5, Example 2). In such situations performance qualification should always be carried out in accordance with ISO 17665 1.

4.1 General attributes

Table 1 — General attributes

Attribute	Code
Design	a
Weight	b
Material	c
Sterile barrier system	d

4.2 Detailed attributes

The following attributes provide detail for characterizing a medical device and a sterilization process. Increased resistance to steam penetration is indicated by ascending code numbers.

Some attributes will be specified by the manufacturer of the medical device and others by the user. The manufacturer of a medical device will usually specify the attributes needed by the user to assess its steam penetration resistance and to select a processing category for a specific sterilizer and sterilization process. Both the resistance and the category should be reassessed when the medical device is to be combined with others in a sterile barrier system and/or packaging system.

The sterilization process should be qualified to verify that the required lethality will be delivered to all medical devices processed together (see ISO 17665 1 and ISO/TS 17665 2).

4.2.1 Design

For the purpose of identifying a type of sterilization process for reprocessing and assigning a processing category, a medical device should be broadly identified from one or more of the designs described in Table 2. The steam penetration resistance will be different for each design when air is to be removed and replaced by saturated steam. The following should be considered when developing an air removal process.

a1: air is displaced predictably as temperature rises with the introduction of steam. This action is unlikely to be affected by orientation.

a2: instrument may need to be in an open position and an active air removal process may be necessary.

a3: residual air in hollows may cause unpredictable delays to sterilizing conditions. Defined orientation and/or the dilution of air by an active air removal process may be necessary.

a4: inadequate removal of air during the air removal stage of the sterilization process can cause uncertainty in the attainment of sterilizing conditions.

a5: an active air removal process will be required. Condensate resulting from temperature differences within materials, interaction between adjacent medical devices and the quality of steam can cause an adverse effect on the efficiency of air dilution.

a6: an active air removal process will be required. Condensate can cause occlusion, inadequate air removal and inadequate steam penetration.

a7: if an active air removal process is required, develop the sterilization process to the product.

Table 2 — Design

Structure	Code (a)	Example
Solid, hollow	1	Bowl, jug, dish, bottle, chisel, single piece skin retractor, single component empty instrument tray
Pin and box joints	2	Scissor, forceps, needle holder
Lumen	3	Laparoscopic sheath, sucker, cannulated reamer, rigid endoscope, cannulated screws
Porous	4	Linen, filters, gauze
Tubing, moving parts, tortuous paths	5	Power tool hose, silicone tubing, dental hand piece, ear nose throat drill,
Lumen surrounded by a large mass	6	Drill, cannulated screw driver, obturator, ratchet handle, bored handle
Other	7	Pre-filled syringe

4.2.2 Material

The materials used to manufacture a medical device will be either metallic or non-metallic or a combination of both. Typically, metallic materials will have a high thermal conductivity and non-metals will have low thermal conductivity.

Materials with low thermal conductivity exhibit higher temperature differences throughout the material when compared to materials with high thermal conductivity. Both types of material present challenges to the sterilization process. The moisture content of the material may also influence the heat transfer into the prod uct. This should be taken into account during performance qualification with the material in its most challenging state.

When compared to materials with low thermal conductivity, materials with high thermal conductivity and equal heat capacity will:

— initially generate more condensate in a given time period,

— absorb and release energy faster,

— attain a state of equilibrium faster.

Examples of some of the materials used are shown in Table 3.

Table 3 — Materials

Material	Example material	Code (b)
Metal	Stainless steel, carbon steel copper and copper-based alloys. Other metals or combinations of metal.	1
Non-metal	Glass, cellulose, polycarbonate, PVC, PTFE, silicon. Other non metals.	2

4.2.3 Weight

The weight of a medical device, or part of a medical device (if processed separately), or for a collection of medical devices grouped into a single sterile barrier system and/or packaging system, should be assigned to one of the codes indicated in Table 4. This information may be required when judging:

— heat-up time;
— cooling time/drying time;
— exposure time in a mixed weight sterilizer load;
— the stability of a single or composite construction material;
— the amount of condensate and its effect on steam penetration.

Table 4 — Weight

Weight g	Code (c)
Less than 50	1
50 to 499	2
500 to 1.999	3
2.000 and greater	4

4.2.4 Sterile barrier system and/or packaging system

Except when a medical device is to be presented aseptically immediately after being re-processed, it will be contained in a sterile barrier system and/or packaging system prior to it being sterilized [see ISO 11607 (all parts) for code d2 to d4 in Table 5]. When establishing the steam penetration resistance and moisture retention for a medical device or a collection of medical devices, the influence on the combined steam penetration resistance caused by the system and the materials used in its construction should be known. A collection of sterile barrier systems and /or packaging systems are listed in Table 5.

NOTE 1 In some countries local regulations may forbid the sterilization of unwrapped medical devices, in which case code d1 would not apply.

Table 5 — Sterile barrier system and/or packaging system

Sterile barrier system	Code (d)
None	1
Single wrapped/pouch	2
Double wrapped in wrapping material or pouches, double wrapped container or tray, reusable sterilization container according to manufacturers instructions	3
Combination of two or more systems, for example, a reusable sterilization container with an inner sterile barrier system	4

NOTE 2 Information on the intended use of the sterile barrier systems will be available from the manufacturer. The effect of combining two or more systems (d4) may require additional performance qualification (see ISO 17665-1:2006, Clause 8).

5 Product family (pf)

The product family assigned to a medical device should be based on attributes identified from the ones shown in 4.2. A number of product families that could be established from these attributes are listed in Table 6.

Use Table 6 to assign a product family to a medical device and then from this assignment identify the steam penetration resistance. For each medical device:

— select a level for each attribute a to d;

— establish a match to one of the product families in the table;

— note the product family and then from column ‘e’, the estimate for steam penetration resistance;

— if a match cannot be obtained, establish a new one and then by comparison with established product families and from performance qualification, estimate a steam penetration resistance.

A discussion and estimate for steam penetration resistance for three types of medical devices are shown in 5.1, 5.2 and 5.3. A user may need to establish additional product families for those designs that cannot be characterized into one of the seven designs illustrated in Table 2.

The steam penetration resistance assigned to each product family listed in Table 6 is estimated and judged from the attributes identified in Clause 4. This estimation is first based on the design of the medical devices in the family and then adjusted if influenced by the other attributes. A procedure set will often contain a range of medical devices and components each assigned a different product family and a different steam penetration resistance. The product family assigned to a procedure set should normally align with the medical device or component assigned the highest steam penetration resistance unless influenced by adjacent medical devices and/or components. Examples are illustrated in Annex B.

The actual steam penetration resistance will depend on the load configuration and any one of the following:

— design of the sterilizer;

— type of operating cycle;

— operational state of the sterilizer witnessed by validation and conformity to the requirements for scheduled periodic tests;

— quality of services delivered to the equipment witnessed by test;

— site.

5.1 Example 1 — pf 1

A shallow, thin wall, metal bowl.

— design: a1,

— material: b1,

— weight: c1,

— sterile barrier system and/or packaging system: d1.

Steam condensing on the bowl will cause a higher concentration of air on its surfaces. This air will be displaced by steam and sterilizing conditions will exist on its surface when the sterilization temperature is measured at the reference measurement point e.g. the chamber drain.

Nominal changes to the non-condensable gases (NCG) in the steam and/or to air leakage into the sterilizer chamber are unlikely to adversely affect the predicted efficiency of the sterilization process.

The estimated steam penetration resistance for this medical device is e1 (see Table 6) based on design a1. The other attributes of the device will not affect this estimation.

5.2 Example 2 — pf 24

A length of thin wall soft plastic tubing.

— design: a5,
— material: b2,
— weight: c1,
— sterile barrier system and/or packaging system: d3.

Sterilization temperature measured at the reference measurement point may not be indicative of sterilizing conditions within the tubing. The following should be considered when selecting a sterilization process and loading configuration:

— an active air removal system is necessary;

— thin wall tubing is susceptible to kinking and collapse;

— occlusion caused by condensate will prevent the removal of air from within the tube and delay or prevent the presence of sterilizing conditions;

— steam condensing on adjacent items can cause an increase in NCG local to the tube and this gas can then be driven by the steam into the tubing;

— air leakage into the sterilizer chamber and/or increased NCG carried by the steam can add to the air already in the tubing and this can then adversely affect the predicted efficiency of the sterilization process.

The estimated steam penetration resistance according to design a5 will be e5. For this medical device, the other attributes listed in Clause 4 will not affect this estimate.

Providing the above considerations are observed when selecting a sterilization process and loading configuration, the estimated steam penetration resistance should remain at e5. However, due to the number of variables listed above, steam penetration resistance may need to be judged from performance qualification (see ISO 17665 1).

5.3 Example 3 — pf 27

Cannulated screw driver with a non-metallic or metallic coated handle.

— design: a6,

— material: b2,

— weight: c2,

— sterile barrier system and/or packaging system: d3.

Poor heat transfer through the surface of the handle will delay the presence of sterilizing conditions in the lumen. This delay can vary for most of the reasons given in example 2.

The estimated steam penetration resistance based on design a6 will be e6. Weight and material may affect this estimate.

Table 6 — Product families

MD	**Attribute**																		**Steam penetration resistance** (estimated)							
PF	Design (a)								Material (b)		Weight (c)				Sterile barrier system and/or packaging system (d)				(e)							
	1	2	3	4	5	6	7	+	1	2	1	2	3	4	1	2	3	4	1	2	3	4	5	6	7	+
1	x								x		x	x	x		x				x							
2	x								x					x	x					x						
3	x									x	x	x	x		x					x						
4	x									x				x	x						x					
5	x								x		x	x	x			x				x						
6	x									x	x	x					x	x			x					
7	x									x			x	x		x	x	x				x				
8			x						x		x	x			x	x	x	x			x					
9			x						x				x	x	x	x	x	x				x				
10			x							x	x	x			x						x					
11			x							x	x	x				x	x	x				x				
12			x							x			x	x		x	x	x					x			
13				x						x	x				x	x					x					
14				x						x	x						x	x				x				
15				x						x		x	x	x			x						x			
16		x							x		x				x					x						
17		x							x		x						x	x			x					
18		x								x	x				x					x						
19		x								x	x					x	x	x			x					
20					x				x		x				x							x				
21					x				x		x	x				x	x	x					x			
22					x					x	x	x			x								x			
23					x				x				x	x		x	x	x					x			
24					x					x	x	x				x	x	x					x			
25					x					x			x	x		x	x	x					x			
26						x			x	x			x	x		x	x	x						x		
27						x			x			x	x		x	x	x	x					x			
28						x				x		x			x	x	x	x						x		
29[a]							x		x	x															x	
+																										

[a] Special - sterilization process should be developed and qualified.
+ New product families that may be identified by the user.

6 Processing category

The medical devices included in a processing category should be based on product family and data that establish the efficiency of a specific sterilizer and its sterilization process for the processing category.

Medical devices of widely different attributes combined in the same processing category can cause an increase in the predicted steam penetration resistance. Based on the design of the individual instruments, the penetration resistance for the general orthopaedic set described in B.4 would be e2. However, due to the sterile barrier system, high total weight of the set, condensate collection, unpredictable air retention and susceptibility to an increase in air leakage into the sterilizer chamber or to the non-condensable gases contained in the steam, the steam penetration resistance for the general orthopaedic set is estimated as e5. The effect on the efficiency of the sterilization process from such combinations and changes should be known for each item contained in the processing category.

One example of how to designate a processing category for a number of procedure sets is illustrated in Annex D.

7 Sterilization process parameters

The maximum values for the process parameters a medical device can be safely exposed to during a moist heat sterilization process should not exceed those specified by the medical device manufacturer (see Annex A).

8 Additional considerations

8.1 Services

Variations in the quality of the services used during the delivery of a sterilization process can affect the efficiency of the sterilization process. Variations can also affect steam penetration resistance, levels of contaminants and the shelf life of some of the medical devices subjected to the sterilization process. The quality of the steam service should be as described in ISO/TS 17665 2:2009, A.11.2 and Table A.2.

8.2 Process selection

A sterilization process consists of a number of prescribed stages carried out in a controlled sequence. The process variables and process parameters for each stage will define the type of medical device, processing category and load configuration that can be sterilized. The first stage will be designed to ensure that for a range of processing categories and load configurations, specified parts of each medical device will be sterile after exposure in stage two of the sterilization process. Returning to atmospheric conditions for use is carried out in the third stage.

In health care facilities, most medical devices are sterilized by saturated steam and the three stages of a sterilization process are, sequentially, air removal, sterilizing and drying. The design for the air removal stage will be based on the ease and way in which air can be removed from the surfaces of each medical device in the sterilization load. A simple air removal system will be passive and rely on gravity displacement of air resulting from the different densities of air and steam. This type of air removal system is unsuitable if air can be trapped, such as in a packaging system or a lumen. The alternative to gravity air removal is active air removal. Active air removal is achieved by using steam, vacuum pump or pressurized water as a power source to generate a series of pressure changes which can be below atmospheric pressure, above atmospheric pressure, or a combination of both. Upper and lower pressure levels, the number of changes and the characteristics of each change will be based on the type of medical device, the steam penetration resistance (see Table 6) and its processing category. Air removal should ensure residual air in the sterilizer chamber and on the surfaces of the sterilizer load is insufficient to affect the efficiency of sterilization.

Air leakage into the sterilizer chamber and non-condensable gases in the steam will adversely affect the efficacy of the air removal stage. It can also be adversely affected if medical devices of widely differing conductivity and/or weight are included in the same processing category.

Stage two will start at a specified minimum sterilizing temperature and exposure at this temperature should be the minimum specified for the holding time. Additional exposure to allow for temperature equilibration may be required when a high weight medical device is to be sterilized.

Stage three will be designed such that after the completion of drying, (normally by vacuum), filtered air will restore the pressure in the sterilizer chamber to atmospheric pressure. The duration of the drying stage will depend on the presentation and weight of each item of the sterilization load.

Annex A
(informative)
Process parameters

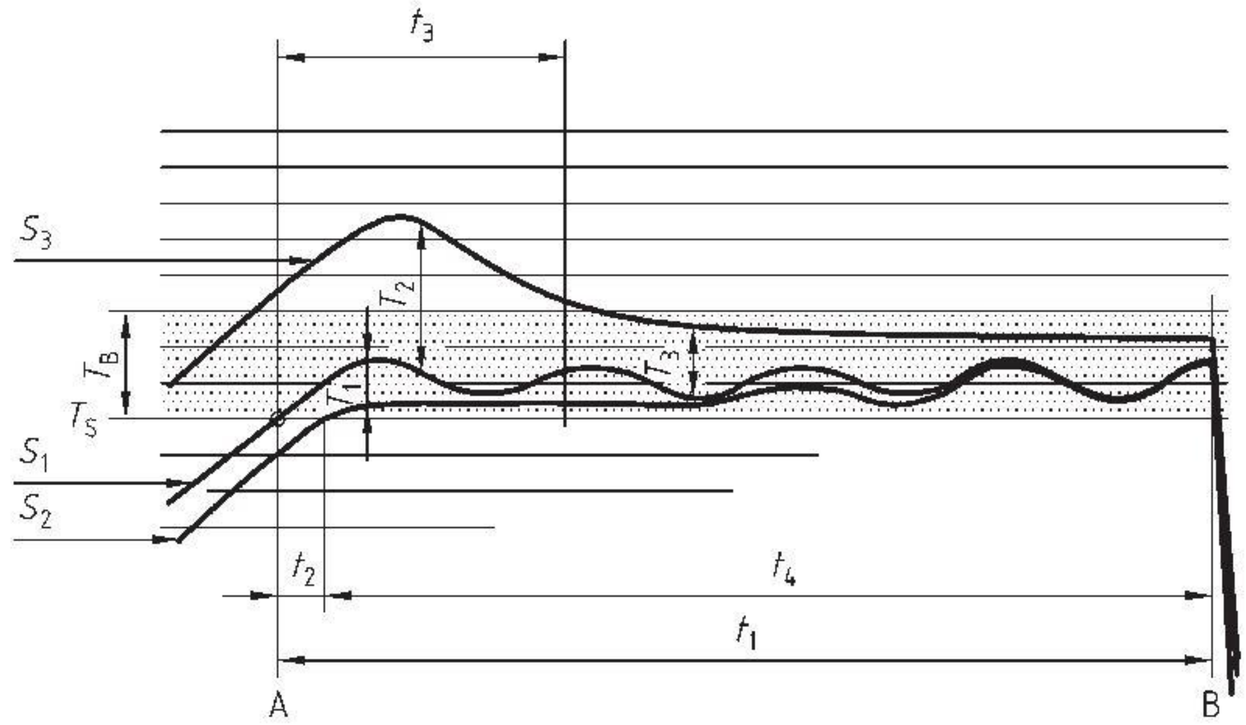
A.1 The critical process variables for a moist heat sterilization process are temperature, time and presence of moisture (see ISO 17665 1). In order for a satisfactory process to be engineered other process parameters will need to be considered such as pressure, rates of pressure and temperature change and dwell times.

A.2 A medical device should not be exposed to process parameters that can adversely affect functional efficiency, therapeutic value and shelf life.

A.3 Process parameters used to ensure that a minimum sterility assurance is routinely obtained may be determined from either a parametric or a biological approach as described in ISO/TS 17665 2:2009, Annexes A and B respectively. Determining a process based on product bioburden considerations is discussed in ISO 17665 1, 7.3 and 8.5.

A.4 The tests described in ISO/TS 17665 2, Annex A, are prescribed for a parametric approach and are used to verify a minimum performance for a specific sterilizer. The data from these tests are used to establish the process parameters listed in A.1 and A.2 and to confirm that air and non-condensable gas remaining in a test load after the completion of the air removal stage will be insufficient to prevent the presence of saturated steam on all the surfaces of the test piece, including concealed surfaces that are open to the sterilizer chamber. The test piece and the performance requirements for these tests represent a high steam penetration resistance (see Table 6). Figure A.1 illustrates a temperature profile for the small load test (see ISO/TS 17665 2, Annex A).The difference in temperature between S1 and S2 can be used to judge the presence of saturated steam.

If the sterilization process and the process parameters identified from these tests are to be used to sterilize a medical device with a higher steam penetration resistance then data should be available to justify this decision. The rationale for this decision should be documented.



Key

A	start of plateau period
B	end of plateau period
Ts	sterilization temperature
TB	sterilization temperature band
S1	reference point
S2	centre of test piece
S3	50mm above test piece
T1	maximum difference
T2	maximum difference – first 60s
T3	maximum difference – after 60s
t1	plateau period
t2	equilibration time
t3	60s
t4	holding time

Figure A.1 — Performance requirements: Small load test

A.5 Medical devices that have similar steam penetration resistance but which are characterized by attributes that are widely different may require exposure to dissimilar process parameters. If they are to be included in the same processing category such as in a procedure set, process parameters according to A.1 and A.2 should be verified.

A.6 While steam condensate remaining within a sterile barrier system may be used to identify a failure of the sterilization process, it may also be indicative of additive influence on steam penetration resistance. One or a combination of the following can be the cause:

— sterilizer chamber architecture;

— design and materials used to manufacture the sterile barrier system;

— load configuration;

— combination of high and low weight medical devices;

— water contained in the steam;

— operating cycle.

For some types of medical devices it may be necessary to include:

a) apreheating prior to pressure changes for high weight devices;

b) delays between pressure changes to allow equalization of pressure and temperature in small diameter lumens;

c) a high vacuum (e.g. 2kPa) prior to pressure changes to minimize the inclusion of water in open ended tubing;

d) rate control for pressure changes to minimize crazing in thick walled plastic medical devices;

e) changes to the load configuration for a reduction in moisture retention.

Annex B
(informative)
Characterization of a procedure set — Examples

The following are examples and illustrate the combination of various medical devices in order to derive product families.

B.1 Assessment/extraction set (oral)

B.1.1 General

The assessment/extraction set comprises a number of individual items as illustrated in Figure B.1, detailed in Table B.2, and analysed in Table B.3. Assessment of the set is in accordance with Clause 4 and is as follows.

— The design of the items in the set varies from simple to moderately complex. Item 8, (surgical suction tip) has a lumen, a design classification of a3 and an estimated steam penetration resistance of e3, the highest in the set.

— Materials used comprise both metal and plastic. The tray is made from polycarbonate, a material that has a low thermal conductivity and deemed to present the greatest challenge. This material has a classification b2 and an estimated steam penetration resistance e2.

— The average weight of the items is 25g. The total weight is 150g and classified as c2.

— Crepe paper wrap is used for the sterile barrier system. This has a classification of d3 and a steam penetration resistance of e3.

Figure B.1 — Assessment/extraction set

Table B.2 — Content of assessment/extraction set

Item	Description	Quantity
1	Tray blue plastic	1
2	Tray liner 130 x 180 cm (not shown)	1
3	Mirror dental	1
4	Dental probe	1
5	Forceps	1
6	Syringe	1
7	Suction adaptor	1
8	Surgical suction tip	1
9	Tray tag	1
10	White crepe 60 x 60 (not shown)	2

Table B.3 — Analysis: assessment/extraction set

Attribute	Description	Code	Steam penetration resistance (estimated)
General description	A collection of solid instruments placed on to a liner in a plastic tray and double wrapped, OR A similar collection of solid instruments placed in a paper mache tray and left unwrapped. Total weight approximately 150g		e3 e1
Design	Solid Perforated polycarbonate tray Lumen instrument (suction tip)	a1 a2 a3	e1 e2 e3
Material	Stainless steel Polycarbonate (tray)	b1 b2	e1 e2
Weight	Average 25g	c1	e1
Sterile barrier system and/or packaging system	None Crepe paper	d1 d3	e1 e3

B.1.2 Product family

The product family assigned to the assessment /extraction set is PF 8. Analysis of the set is illustrated in Table B.4. The assignment of PF8 has been based on item 8 (see Table B.2) noting that the additive influence from the polycarbonate tray and the low weight of adjacent medical devices in the set will be insufficient to affect the estimated steam penetration resistance, e3 for this medical device.

Table B.4 — Product family — Classification based on estimates: Assessment/extraction set

MD	Attribute																									
																			Steam penetration resistance (estimated)							
PF	Design (a)								Material (b)		Weight (c)				Sterile barrier system and/or packaging system (d)				(e)							
	1	2	3	4	5	6	7	+	1	2	1	2	3	4	1	2	3	4	1	2	3	4	5	6	7	+
8	x	x	x							x	x				x		x		x	x	x					

B.2 Cystoscope, bridge and tap set

B.2.1 General

The bridge and tap set comprises a number of individual items as illustrated in Figure B.2, detailed in Table B.5, and analysed in Table B.6.

Assessment of the set is in accordance with Clause 4 and is as follows:

— the design of the items in the set varies from simple to complex. Item 3, (cystoscope-urethroscope sheath) has a small lumen, a design classification a5 and an estimated steam penetration resistance of e5, the highest in the set.
— materials used comprise both metal and plastic. The matting tray is made of silicone, has a low thermal conductivity and deemed to present the greatest challenge. This material has a classification b2 and an estimated steam penetration resistance a3.
— the total weight is 200g and the individual Items range in weight from 5g up to 100g. The classification is c2.
— the sterile barrier system consists of a perforated aluminium tray and lid double wrapped in crepe paper. This has a classification of d3 and a steam penetration resistance of e3.

Figure B.2 — Cystoscope, bridge and tap set (22 FG)

Table B.5 — Content of cystoscope, bridge and tap set (22 FG)

Item	Description contents list	Quantity
1	Sterilization tray	1
2	Silicone mat	1
3	Cystoscope- urethroscope sheath	1
4	Obturator	1
5	Stopcock for cystoscope-urethroscope	2
6	Spring cap	3
7	Telescope bridge	1
8	Stopcock for telescope bridge	1
9	Sealing cap	1
10	Tray tag (not shown)	1
11	White crepe 90 x 90 (not shown)	2

Table B.6 — Analysis: cystoscope, bridge and tap set (22 FG)

Attribute	Description	Code	Steam penetration resistance (estimated)
General description	Rigid endoscope with parts, supported on silicone mat, contained in a perforated container and lid and double wrapped in crepe paper. Total weight approximately 200 g		e5
Design	Solid Perforated aluminium tray Lumen	a1 a1 a5	e1 e1 e5
Material	Stainless steel, aluminium Silicone	b1 b2	e1 e3
Weight	5 g to 100 g	c1 c2	e1 e1
Sterile barrier system and/or packaging system	Crepe paper	d3	e3

B.2.2 Product family

The product family assigned to the cystoscope, bridge and tap set is PF24. Analysis of the set is illustrated in Table B.7. The assignment of PF24 has been based on item 3 (see Table B.5) noting that the additive influence from the silicone mat and the low weight of adjacent medical devices in the set will be insufficient to affect the estimated steam penetration resistance, e5 for this medical device.

Table B.7 — Product family — Classification based on estimates: Cystoscope, bridge and tap set (22 FG)

MD	**Attribute**																											
PF	Design (a)								Material (b)		Weight (c)				Sterile barrier system and/or packaging system (d)				**Steam penetration resistance** (estimated)							
	1	2	3	4	5	6	7	+	1	2	1	2	3	4	1	2	3	4	1	2	3	4	5	6	7	+
24	x				x				x	x	x	x					x		x		x		x			

B.3 Cataract ophthalmic No. 6 set

B.3.1 General

The cataract ophthalmic No. 6 set comprises a number of individual items as illustrated in Figure B.3, detailed in Table B.8, and analysed in Table B.9.

Assessment of the set is in accordance with Clause 4 and is as follows.

— The design of items in the set comprise simple pin joints, box locks and solid construction. Items with a pin joint or box lock, (scissors and some forceps) present the highest challenge due to close mating surfaces. They have a design classification of a2 and an estimated steam penetration resistance of e2.

— Materials used comprise both metal and plastic. The silicone and polycarbonate components have low thermal conductivity and are deemed to present the greatest challenge. Both of these materials have a classification b2 and an estimated steam penetration resistance e3.

— The weight of individual items in the set range from 20 g up to 30 g. Classification is c2.

— The sterile barrier system comprises a perforated polycarbonate tray and lid, double wrapped with crepe paper. This has a classification of d3 and a steam penetration resistance of e3.

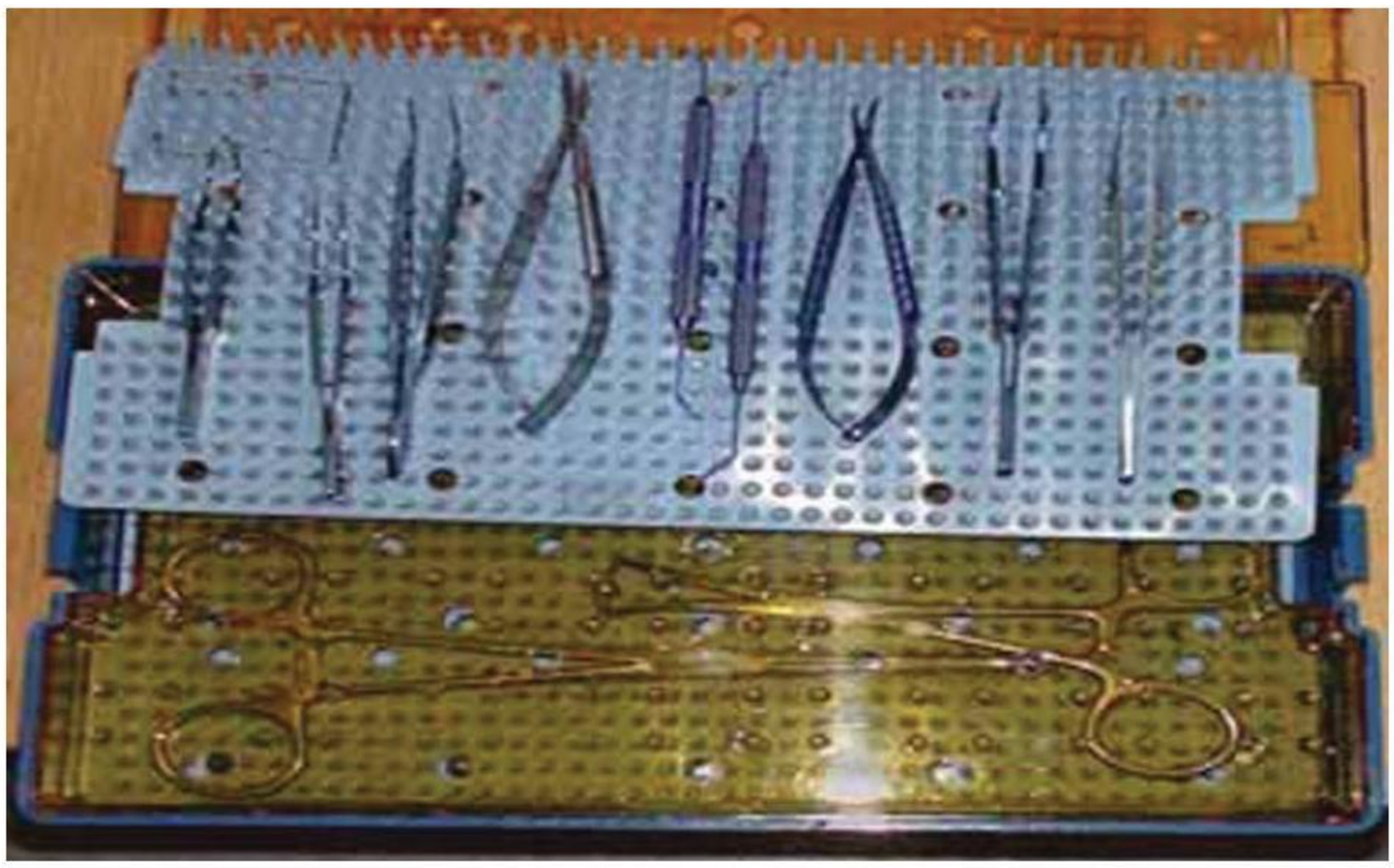


Figure B.3 — Cataract ophthalmic No. 6 set

Table B.8 — Content of cataract ophthalmic No. 6 set

Item	Description	Quantity	Item	Description	Quantity
1	Tray with lid	1	11	Forceps, lens introducing	1
2	Speculum, sliding (not visible)	1	12	Forceps, sponge holding 18cm	1
3	Forceps, fine point	1	13	Clip towel, non-perforating	1
4	Forceps, micro curved	1	14	Scissors, nurses, small (not visible)	1
5	Forceps, capsular	1	15	Scissor, iris, straight, 90mm (not visible)	1
6	Scissors	1	16	Eye lid retractor	1
7	Spatula/rotator/manipulator	1	17	Tray tag (not shown)	1
8	Hook chopper, straight pull	1	18	White crepe 60 x 60 (not shown)	2
9	Needle holder, micro	1	19	Silicone mat	2
10	Forceps, lens holding	1			

Table B.9 — Analysis: Cataract ophthalmic No. 6 set

Attribute	**Description**	**Code**	**Steam penetration resistance** (estimated)
General description	Small instruments supported on two layers of silicone mat in a perforated plastic tray with lid. Double wrapped in crepe paper		e3
Design	Solid Pin joint	a1 a2	e1 e2
Material	Stainless steel, titanium Silicone, polycarbonate	b1 b2	e1 e3
Weight	20 g to 30 g	c1	e1
Sterile barrier system and/or packaging system	Crepe paper	d3	e3

B.3.2 Product family

The product family assigned to the cataract ophthalmic No. 6 set is PF19. Analysis of the set is illustrated in Table B.10. The assignment of PF19 has been based on item 18 (see Table B.8) noting that the additive influence from the silicone mat and the low weight of the medical devices in the set will be insufficient to affect the estimated steam penetration resistance, e3 for the crepe paper sterile barrier system.

Table B.10 — Product family — Classification based on estimates: Cataract ophthalmic No. 6 set

MD	**Attribute**																									
PF	Design (a)								Material (b)		Weight (c)				Sterile barrier system and/or packaging system (d)				**Steam penetration resistance** (estimated)							
	1	2	3	4	5	6	7	+	1	2	1	2	3	4	1	2	3	4	1	2	3	4	5	6	7	+
19	x	x							x	x	x						x		x	x	x					

B.4 General orthopaedic set

B.4.1 General

The general orthopaedic set comprises a number of individual items as illustrated in Figure B.4, detailed in Table B.11, and analysed in Table B.12.

Assessment of the set is in accordance with Clause 4 and is as follows.

— The design of items in the set comprise simple pin joints, box locks and solid construction. Items with a pin joint or box lock, (scissors and some forceps) present the highest challenge due to close mating surfaces. They have a design classification of a2 and an estimated steam penetration resistance of e2.

— The material used for each medical device is stainless steel. This has a classification b2 and an estimated steam penetration resistance e3.

— The weight of individual items in the set range from 50 g up to 800 g and the total weight of the set is 8.000 g. Classification is c2.

— The sterile barrier system comprises a perforated aluminium tray, double wrapped with a laminated sheet containing a polymer centre crepe paper. The classification is d3 and the steam penetration resistance is e3.

Figure B.4 — General orthopaedic set

Table B.11 — Content of general orthopaedic set

Item	Description	No.	Item	Description	No.
1	Instrument tray	1	16	Hook, bone sharp	2
2	Tray liner 30 cm x 50 cm	1	17	Elevator	1
3	Knife handle	5	18	Lever, bone	4
4	Forceps, sponge holding 24 cm	5	19	Retractor, small 6 mm	2
5	Clip, towel non-perforating	6	20	Retractor, medium 13 mm	2
6	Forceps, dissecting 1/2 teeth 14/15cm	2	21	Mallet ring	1
7	Scissors, curved/straight 18 cm	4	22	Retractor, self-retaining	2
8	Scissors, stitch	1	23	Cutter, bone 18 cm	1
9	Forceps, artery curved 15 cm	4	24	Rongeur	2
10	Forceps, artery 18 cm	8	25	Bag clip	1
11	Forceps, tissue 3/4 teeth	2	26	Prep sponge	5
12	Needle holder 18 cm	3	27	Pin	2
13	Dissector 19 cm	1	28	Tray tag (not shown)	1
14	Dissector	1	29	Tray wrap non-woven 2 ply wrapper 150 cm x 180 cm (not shown)	4
15	Spoon 14 cm	1			

Table B.12 — Analysis -general orthopaedic set

Attribute	Description	Code	Steam penetration resistance (estimated)
General description	Large number of different types and weights of instruments assembled onto a tray liner in a metal tray. Double wrapped with nonwoven wrapper x2 Total weight approximately 8.000 g		e5
Design	Solid Perforated aluminium tray Pin/box joint	a1 a1 a2	e1 e1 e2
Material	Stainless steel	b1	e1
Weight	50 g to 800 g	c1 c2 c3	e1 e1 e1
Sterile barrier system and/or packaging system	Single use 2 ply wrapper	d3	e3

B.4.2 Product family

The product family assigned to the general orthopaedic set is PF17. Analysis of the set is illustrated in Table B.13. The high weight of the set can cause additive influence on the steam penetration resistance predicted for the pin and box designs and for this reason the estimated steam penetration resistance is increased to e5.

Table B.13 — Product family — Classification based on estimates: General orthopaedic set

MD	Attribute																		Steam penetration resistance (estimated)							
PF	Design (a)								Material (b)		Weight (c)				Sterile barrier system and/or packaging system (d)				(e)							
	1	2	3	4	5	6	7	+	1	2	1	2	3	4	1	2	3	4	1	2	3	4	5	6	7	+
17	x	x							x				x						x	x	x		x			

B.5 General laparoscopy set

B.5.1 General

The general laparoscopy set comprises a number of individual items as illustrated in Figure B.5, detailed in Table B.14, and analysed in Table B.15.

Assessment of the set is in accordance with Clause 4 and is as follows.

— The design of items in the set comprise simple pin joints, box locks, long lumens and solid construction. The laparoscope has a design classification of a2 and an estimated steam penetration resistance of e2.

— Materials used comprise both metal and plastic. The silicone component with its low thermal conductivity presents the greatest challenge. This has a classification b2 and an estimated steam penetration resistance e3.

— The weight of individual items in the set range from 20 g up to 400 g and the total weight is 4 250 g. Classification is c2.

— The sterile barrier system comprises a perforated stainless steel tray, double wrapped using laminated sheets that contain a polymer centre crepe paper. Classification is d3 and the steam penetration resistance is e3.

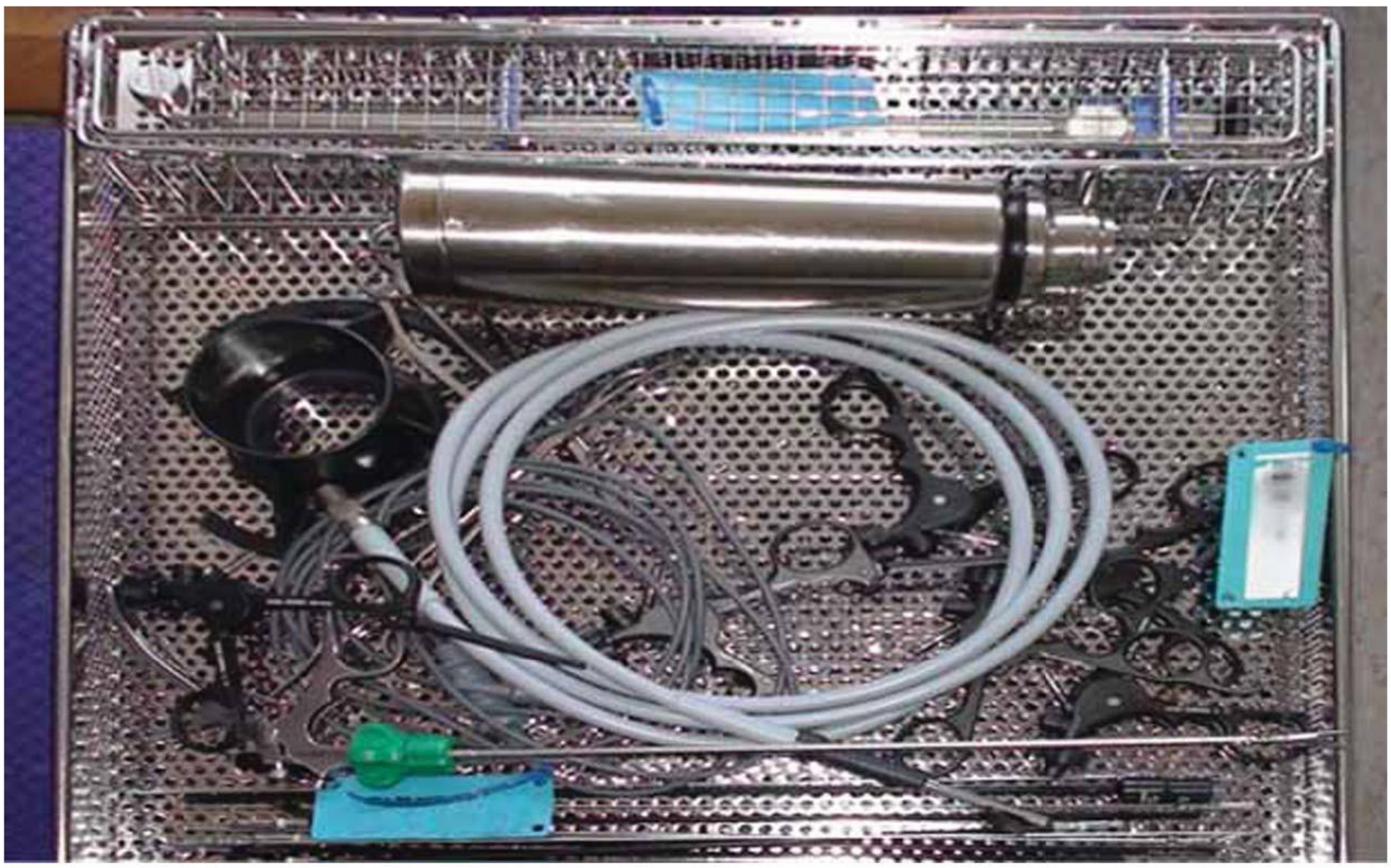


Figure B.5 — General laparoscopy set

Table B.14 — Content of general laparoscopy set

Item	Description	No.	Item	Description	No.
1	Instrument tray	1	10	Click line handle, ratchet	3
2	Tray liner 457 mm x 610 mm	1	11	Diathermy hook, right angled	1
3	Flask metal	1	12	Forceps	3
4	Scope warmer base	1	13	Grasper	3
5	Telescope 10 mm 0° in metal basket	1	14	Scissor insert	1
6	Light lead	1	15	Diathermy lead	1
7	Forceps, tissue 2/3 teeth 18 cm	2	16	Clip applier	1
8	Click line sheath	6	17	Tray tag (not shown)	1
9	Click line handle, non-ratchet	3	18	Tray wrap nonwoven 2 ply wrapper. 150 cm x 180 cm (not shown)	2

Table B.15 — General laparoscopy set

Attribute	Description	Code	Steam penetration resistance (estimated)
General description	Combination of differently designed instruments manufactured from single and composite materials. Assembled on to a tray liner in a perforated metal tray. Double wrapped nonwoven 2 ply wrapper. Total weight approximately 4.250 g		e5
Design	Solid Perforated stainless steel tray Hollow Electrical leads Pin/box joint Lumen	c1 c1 c3 c3 c2 c5	e1 e1 e3 e2 e2 e5
Material	Stainless steel PTFE, polycarbonate, silicone	a1 a2	e1 e3
Weight	20 g to 400 g	b1 b2	e1 e2
Sterile barrier system and/or packaging system	Non-woven 2 ply wrapper	d3	e3

B.5.2 Product family

The product family assigned to the general laparoscopy set is PF22. Analysis of the set is illustrated in Table B.16. The assignment of PF22 is based on the laparoscope.

Table B.16 — Product family — Classification based on estimates: General laparoscopy set

MD	**Attribute**																		**Steam penetration resistance** (estimated)							
PF	Design (a)								Material (b)		Weight (c)				Sterile barrier system and/or packaging system (d)				(e)							
	1	2	3	4	5	6	7	+	1	2	1	2	3	4	1	2	3	4	1	2	3	4	5	6	7	+
22	x	x	x		x				x	x	x	x					x		x	x	x		x			

B.6 LCS knee set (1 of 6)

B.6.1 General

This LCS knee set comprises a number of individual items as illustrated in Figure B.6, detailed in Table B.17, and analysed in Table B.18.

Assessment of the set is in accordance with Clause 4 and is as follows.

— The design of items in the set are solid, item 9 (slap hammer) has two components which slide against each other to create a tortuous path. Item 9 has a design classification a6 and an estimated steam penetration e6.

— Materials used comprise both metal and plastic-coated metal. The silicon coating with its low thermal conductivity presents the greatest challenge. This has a classification b2 and an estimated steam penetration resistance e3.

— The weight of individual items in the set range from 50 g up to 600 g and the total weight is 9 600 g. Classification is c3 for the heaviest item and c4 for the set.

— The sterile barrier system comprises a perforated stainless steel tray, double wrapped using non-woven 2 ply wrapper. Classification is d3 and the steam penetration resistance is e3.

Figure B.6 — LCS knee (set 1 of 6)

Table B.17 — Contents: LCS knee (set 1 of 6)

Item	Description	No.	Item	Description	No.
1	Instrument tray	1	10	Visualisation wing	1
2	Tray liner 30 cm x 50cm	1	11	Rasp straight	1
3	Knife handle	1	12	Punch	1
4	Clamp, ankle with spring	1	13	Rod	1
5	Block, resection tibial	2	14	Resection guide, tibial	1
6	Block, cutting v-v 2 degree	1	15	Punch pilot, centre tibial	1
7	Depth guide 2/6mm	1	16	Retractor	1
8	Impactor, femoral	1	17	Tray tag (not shown)	1
9	Slap hammer	1	18	Tray wrap non-woven 2 ply wrapper 150 cm x 180 cm (not shown)	2

Table B.18 — Product family — Classification based on estimates: LCS knee (set 1 of 6)

Attribute	Description	Code	Steam penetration resistance (estimated)
General description	Comprises a collection of medium to heavy instruments made from single and composite materials. Arranged on a tray liner in a perforated metal tray. Double wrapped using non-woven 2 ply wrapper. Total weight approximately 9 600 g		e6
Design	Solid Solid from composite stainless steel and polycarbonate Perforated stainless steel tray Hollow Electrical leads Pin/box joint Lumen surrounded by large metal mass	a1 a1 a1 a3 a3 a3 a6	e1 e2 e1 e3 e2 e2 e6
Material	Stainless steel PTFE, polycarbonate	b1 b2	e1 e3
Weight	50 g to 600 g	c2 c3	e1 e4
Sterile barrier system and/or packaging system	Non-woven 2 ply wrapper	d3	e3

B.6.2 Product family

The product family assigned to the LCS knee (set 1 of 6) is PF26. Analysis of the set is illustrated in Table B.19. The assignment of PF25 and steam penetration resistance, e6 is based on the slap hammer and the impactor femoral. This latter item without the coating would be e2, however the low heat transfer through the plastic and high heat transfer through the metal causes a cyclic temperature change on the plastic surface and an estimated increase to e5.

Table B.19 — Product family — Classification based on estimates: LCS knee (set 1 of 6)

MD	**Attribute**																		**Steam penetration resistance** (estimated)							
PF	Design (a)								Material (b)		Weight (c)				Sterile barrier system and/or packaging system (d)				(e)							
	1	2	3	4	5	6	7	+	1	2	1	2	3	4	1	2	3	4	1	2	3	4	5	6	7	+
26	x		x		x	x			x	x		x	x				x		x	x	x	x		x		

B.7 Femur repair and nail extraction set

B.7.1 General

This femur repair and nail extraction set comprises a number of individual items as illustrated in Figure B.7, detailed in Table B.20, and analysed in Table B.21.

Assessment of the set is in accordance with Clause 4 and is as follows.

— The design of items in the set vary from solid, simple and complex. Item 14, (luminous handle entry portal) has the highest estimated challenge due to the high mass of silicone around a metallic lumen. Classification for this item is a6 and the steam penetration resistance is e7.

— Materials used comprise both metal and plastic-coated metal. The silicon coating with its low thermal conductivity presents the greatest challenge. This has a classification b2 and an estimated steam penetration resistance e3.

— The weight of individual items in the set range from 40 g up to 700 g and the total weight is 10 700 g. Classification is c3 for the heaviest item and c4 for the set.

— The sterile barrier system consisted of a perforated inner tray contained within a rigid reusable sterilizing container. Classification is d3 and the steam penetration resistance is e3.

Figure B.7 — Femur repair and nail extraction set

Table B.20 — Content: Femur repair and nail extraction set

Item	Description	No	Item	Description	No
1	Reducer	1	18	Reamer pilot nose	15
2	Flexible reamer extender	1	19	Slotted hammer	1
3	Flexible reamer shaft	1	20	T-handle	1
4	Luminous ruler black	1	21	Awl	1
5	Flexible reamer	1	22	Protector skin	1
6	Gripper	1	23	Screw length sleeve	1
7	T-handle	1	24	Guide bolt wrench	1
8	Reducer slot orientation	1	25	Obturator	1
9	Connector mini	1	26	Driver multipurpose	2
10	Trinkle to mini connector	1	27	Screwdriver hexagonal long	6
11	Connector AO mini	1	28	Handle screw release	1
12	Trocar T-handle	1	29	Depth gauge screw	2
13	Tube entry portal	1	30	Targeter	1
14	Luminous handle entry portal	1	31	Drill sleeve inner metal 4 mm	2
15	Awl cannulated	1	32	Drill sleeve outer gold	2
16	Impactor	1	33	Rigid reusable sterilization container	1
17	Entry tool honeycomb	1			

Table B.21 — Analysis: Femur repair and nail extraction set

Attribute	Description	Code	Steam penetration resistance (estimated)
General description	A range of centrally bored handles, reamers, drills, spanners, hammer, measuring devices and component parts packaged in a large metal sterilizing container with paper filters. Total weight approximately 10,7 kg	varies	e7+
Design	Solid metallic Solid non-metallic Solid composite (metallic and non-metallic) Luminous metallic Luminous non-metallic Luminous composite (metallic and non-metallic) Polycarbonate Pin joint Slip joint Perforated stainless container	a1 a2 a3 a3 a5 a6 a3 a2 a2 a1	e1 e2 e3 e5 e6 e7 e3 e2 e2 e1
Material	Stainless steel (coated & uncoated) Anodized alloys Carbon fibre Silicone Polycarbonate	b1 b1 b2 b2 b2	e1 e1 e3 e3 e3
Weight	Items >40 g Items >50 g but <500 g Items <700 g	c1 c2 c3	e1 e2 e3
Sterile barrier system and/or packaging system	Rigid reusable sterilization container	d3	e3

B.7.2 Product family

The product family assigned to the femur repair and nail extraction set is PF29. Analysis of the set is illustrated in Table B.22. The assignment of PF29 and steam penetration resistance, e7 is based on item 14 (luminous handle entry portal). The high weight of the set will generate condensate, slow the removal of air within the set and cast uncertainty on the efficiency of air removal from the handle.

Table B.22 — Product family — Classification based on estimates: Femur repair and nail extraction set

MD	Attribute																		Steam penetration resistance (estimated)							
PF	Design (a)								Material (b)		Weight (c)				Sterile barrier system and/or packaging system (d)				(e)							
	1	2	3	4	5	6	7	+	1	2	1	2	3	4	1	2	3	4	1	2	3	4	5	6	7	+
29	x	x	x		x	x	x		x	x	x	x	x				x									x	

Annex C
(informative)
Designating a processing category

1) Verify the types of medical devices the sterilizer and its sterilization process is designed to process.

2) Group these medical devices into product families in accordance with Clause 5.

3) Verify that the sterilizer has been subject to installation qualification and operational qualification (see ISO 17665 1 and ISO/TS 17665 2) and that data remains valid (see ISO 17665 1:2006, Clause 12).

4) Confirm that process parameters delivered by the sterilization process will not exceed those specified by the manufacturer of each medical device.

5) Estimate the steam penetration resistance for each product family and/or procedure set to be sterilized in accordance with Clauses 4 and 5.

6) Identify, from the product families to be sterilized, the ones whose steam penetration resistance estimated in Clause 5 does not exceed the maximum for the sterilizer identified in list item 3.

7) Noting the guidance given in subclause 4.2 and Clauses 6 and 8, group the product families identified in Clause 6 into processing categories.

8) Continue to note the guidance given in subclause 4.2, Clauses 6 and 8 and Annex A and select from each processing category the product family or procedure set identified to have the highest estimated steam penetration resistance.

9) Select from the product families or procedure sets identified in list item 8 the ones that have the same estimated steam penetration resistance.

10) Select from the product families or procedure sets identified in list item 9 the one judged most difficult to sterilize.

11) Select from the products identified in list item 9 the ones that have characteristics (see 3.2, 5, 7 and Annex A) that if combined in the same sterilization load may cause doubt about the efficiency of the sterilization process.

12) Identify from the products selected in list items 10 and 11 a "master product" for the processing category or processing categories they represent. Examples are shown in Annex D, Figures D.8, D.9 and D.10.

13) Confirm that the sterilization process continues to attain the sterilization parameters verified in list item 3 and the daily steam penetration test is registered as a "pass".

14) Using the master product identified in list item 12, and the processing category it was first assigned to, carry out performance qualification using one or a combination of the parametric or biological methods given in ISO 17665 1 and ISO/TS 17665 2.

15) Confirm from the data obtained from list item 14 that process parameters are within the limits, sterilizing conditions have been attained within the master product for the duration

of the hold period and there is no visible and or functional damage to product and packaging.

16) Using the same sterilization process as in list item 14, repeat list items 14 and 15 for the processing categories represented by the master products identified in list item 12.

17) Process parameters for routine reprocessing of each processing category should be nominally the same as list items 13 and 15.

Examples of different processing categories are shown in Annex D. Each example illustrates a number of procedure sets grouped together to form a processing category. The one identified as the master product contains all the sterilization features from each individual family member.Verify the types of medical devices the sterilizer and its sterilization process is designed to process.

NOTE For routine monitoring and control a master product may be supplemented by process information derived from a fixed device, such as an air detector or a portable device such as a PCD (see ISO 17665 1:2006, Clause 10). The challenge to the sterilization process from the device chosen should be at least equal to the challenge from the master product it supplements.

Annex D
(informative)
Processing categories — Examples

D.1 General instruments

The processing category illustrated in Figure D.1 contains six sets, each assessed in accordance with Clause 4 and detailed in D.1.1 to D.1.12.

Key

1 family member 1
2 family member 2
3 family member 3
4 family member 4
5 family member 5
6 family member 6

Figure D.1 — Processing category: General instruments

D.1.1 Assessment of family member 1

Family member 1 is assessed as follows (see Tables D.1 and D.2).

— The design of items in the set comprise simple pin joints, box locks and cotton fabric. The cotton presents the highest challenge resulting in a classification a2 and an estimated steam penetration resistance of e2.

— The material used is stainless steel and cotton. Based on the cotton, classification is b2 and estimated steam penetration resistance is e3.

— The average weight of the items in the set range is 25 g. Classification is c1.

— The sterile barrier system comprises a metal tray, double wrapped in a single use 2 ply wrapper. Classification is d3 and the steam penetration resistance is e3.

Table D.1 — Content: Family member 1

Item	Description	No.	Item	Description	No.
1	Vag retractor	2	8	Basin small round	1
2	Forceps	4	9	Medicine cup	1
3	Needle holder	1	10	Baby blanket	2
4	Sponge stick	2	11	Cotton balls	12
5	Forceps, tissue	1	12	Sponge gauze 4x4	12
6	Surgical towel	1	13	Perforated instrument tray	1
7	Scissors, suture	1	14	Single use 2 ply wrapper	1

Table D.2 — Analysis: Family member set 1

Attribute	Description	Code	Steam penetration resistance (estimated)
General description	Comprises a collection of medium weight instruments made from stainless steel, with a stainless steel basin, arranged on a surgical towel in a perforated metal tray combined with baby blankets, surgical towels and cotton balls wrapped with a single use 2 ply wrapper. Total weight approximately 2.000 g		e4
Design	Solid Perforated tray Porous fabric	a1 a1 a4	e1 e3 e4
Material	Stainless steel Cotton fabric Cotton balls	b1 b2 b2	e1 e3 e3
Weight	Average 25 g	c1	e1
Sterile barrier system and/or packaging system	Single use 2 ply wrapper	d3	e3

D.1.2 Product family

The product family assigned to family member set 1 is PF14. Analysis of the set is illustrated in Table D.3 The assignment of PF14 and steam penetration resistance, e4 is based on the single use 2 ply wrapper.

Table D.3 — Product family — Classification based on estimates: Family member 1

MD	Attribute																									
	Design (a)								Material (b)		Weight (c)				Sterile barrier system and/or packaging system (d)				Steam penetration resistance (estimated) (e)							
	1	2	3	4	5	6	7	+	1	2	1	2	3	4	1	2	3	4	1	2	3	4	5	6	7	+
14	x			x					x	x	x						x		x	x	x	x				

D.1.3 Assessment of family member 2

Family member 2 is assessed as follows (see Tables D.4 and D.5).

— The design of items in the set comprise simple pin joints, box locks, solid metal and some cotton fabric. Cotton presents the highest challenge and this has a classification a2 and an estimated steam penetration resistance of e3.

— The material used is stainless steel and cotton. This has a classification b2 and an estimated steam penetration resistance e3.

— The weight of the items in the set range between 50 g and 500 g and the total weight is 3.960 g. Classification is c2.

— The sterile barrier system comprises a perforated inner tray contained in a rigid reusable container. Classification is d3 and the steam penetration resistance is e3.

Table D.4 — Content: Family member 2

Item	Description	No.	Item	Description	No.
1	Wire cutter	1	6	Rake, sharp	2
2	Eyed obturator	2	7	Rib spreader	2
3	Suction cvd	2	8	Perforated instrument tray	1
4	Retractor	9	9	Rigid reusable sterilization container	1
5	Retractor, self-retaining	1			

Table D.5 — Analysis: Family member set 2

Attribute	Description	Code	Steam penetration resistance (estimated)
General description	Comprises a collection of medium to heavy weight instruments made from stainless steel, arranged on a surgical towel in a perforated metal basket inside a rigid reusable sterilization container. Total weight approximately 3 960 g		e4
Design	Solid Pin and box joints Perforated tray Porous towel	a1 a2 a1 a4	e1 e1 e3 e3
Material	Stainless steel Cotton fabric towel	b1 b2	e1 e3
Weight	50 g to 500 g	c1 c2	e1
Sterile barrier system and/or packaging system	Reusable metal sterilization container	d3	e3

D.1.4 Product family

The product family assigned to family member set 2 is PF14. Analysis of the set is illustrated in Table D.6 The assignment of PF14 and steam penetration resistance, e4 is based on the sterilization container.

Table D.6 — Product family classification based on estimates: family member 2

MD	Attribute																									
PF	Design (a)								Material (b)		Weight (c)				Sterile barrier system and/or packaging system (d)				(e)							
	1	2	3	4	5	6	7	+	1	2	1	2	3	4	1	2	3	4	1	2	3	4	5	6	7	+
14	x	x		x			x		x	x	x	x					x					x				

D.1.5 Assessment of family member 3

Family member 3 is assessed as follows (see Tables D.7 and D.8).

— The design of items in the set comprises simple pin joints, box locks, solid metal and some cotton fabric. Due to additional layers of packaging material around the tissue forceps this item has the highest estimated challenge, is classified a2 and has an estimated steam penetration resistance of e3.

— The material used is stainless steel and cotton. This has a classification b2 and an estimated steam penetration resistance e3.

— The weight of the Items in the set range between 50 g and 250 g and the total weight is 5 400 g. Classification is c2.

— The sterile barrier system comprises a perforated inner tray contained in a rigid reusable container. Classification is d3 and the steam penetration resistance is e3.

Table D.7 — Content: Family member 3

Item	Description	No	Item	Description	No
1	clamp	6	7	scissors	6
2	forceps	31	8	knife handle	3
3	metric ruler	1	9	forceps, tissue	11
4	needle holder	6	10	perforated instrument basket	1
5	retractor	4	11	paper/plastic peel pouch 5x9	1
6	retractor, self-retaining	8	12	rigid reusable sterilization container	1

Table D.8 — Analysis: Family member set 3

Attribute	Description	Code	Steam penetration resistance (estimated)
General description	Comprises a collection of medium to heavy weight instruments made from stainless steel, arranged on a surgical towel in a perforated metal basket inside a rigid reusable sterilization container. Total weight approximately 5.400 g		e7
Design	Solid Perforated tray Pouch with tissue forceps in micro instrument tray sealed inside a rigid reusable sterilization container	a1 a1 a7	e1 e3 e7
Material	Stainless steel Cotton fabric towel	b1 b2	e1 e3
Weight	50 g to 250 g	c1 c2	e1 e1
Sterile barrier system and/or packaging system	Reusable metal sterilization container	d3	e3

D.1.6 Product family

The product family assigned to family member set 3 is PF29. Analysis of the set is illustrated in Table D.9 The assignment of PF29 and steam penetration resistance, e7 is based on the packaging around the tissue forceps.

Table D.9 — Product family classification based on estimates: family member 3

MD	**Attribute**																		**Steam penetration resistance** (estimated)							
PF	Design (a)								Material (b)		Weight (c)				Sterile barrier system and/or packaging system (d)				(e)							
	1	2	3	4	5	6	7	+	1	2	1	2	3	4	1	2	3	4	1	2	3	4	5	6	7	+
29	x						x		x	x	x	x					x		x	x	x				x	

D.1.7 Assessment of family member 4

Family member 4 is assessed as follows (see Tables D.10 and D.11).

— The design of items in the set comprise simple metal bowls, cups and some cotton fabric. The highest challenge is from the sterile barrier system classified d3 with an estimated steam penetration resistance of e3.

— The material used is stainless steel and cotton. This has a classification b2 and an estimated steam penetration resistance e3.

— The weight of the items in the set range between 50 g and 1.000 g and the total weight is 2.700 g. Classification is c3.

— The sterile barrier system comprises single use 2-ply wrappers. Classification is d3 and the steam penetration resistance is e3.

Table D.10 — Content: Family member 4

Item	**Description**	**No**	**Item**	**Description**	**No**
1	Large basin	1	5	Medium basin	1
2	Small basin	1	6	Iodine cup	1
3	Medicine cup	1	7	Single use 2 ply wrapper	1
4	Surgical towel	2			

Table D.11 — Analysis: Family member set 4

Attribute	Description	Code	Steam penetration resistance (estimated)
General description	Comprises a collection of medium weight basins made from stainless steel, arranged with surgical towels separating different basins wrapped with single use 2 ply wrappers Total weight approximately 2.700 g		e3
Design	Solid Cotton fabric towel	a1 a4	e1 e3
Material	Stainless steel Cotton fabric towel	b1 b2	e1 e3
Weight	50 g to 1.000 g	c1 c2 c3	e1 e1 e1
Sterile barrier system and/or packaging system	Single use 2 ply wrappers	d3	e3

D.1.8 Product family

The product family assigned to family member set 4 is PF13. Analysis of the set is illustrated in Table D.12 The assignment of PF13 and steam penetration resistance, e3 is based on the sterile barrier system.

Table D.12 — Product family — Classification based on estimates: Family member 4

MD	Attribute																		Steam penetration resistance (estimated)							
PF	Design (a)								Material (b)		Weight (c)				Sterile barrier system and/or packaging system (d)				(e)							
	1	2	3	4	5	6	7	+	1	2	1	2	3	4	1	2	3	4	1	2	3	4	5	6	7	+
13	x			x					x	x	x	x	x				x				x					

D.1.9 Assessment of family member 5

Family member 5 is assessed as follows (see Tables D.13 and D.14).

— The design of items in the set are solid and tubular. The greatest challenge is the latex tubing category a5 with an estimated steam penetration resistance e5.

— The material used is stainless steel, plastic and latex. This has a classification b2 and an estimated steam penetration resistance e3.

— The weight of the items in the set range between 50 g and 250 g and the total weight is 500 g. Classification is c3.

— The sterile barrier system comprises a paper peel pouch. Classification is d3 and the steam penetration resistance is e3.

Table D.13 — Content: Family member 5

Item	Description	No	Item	Description	No
1	Suction bottle	1	3	Rubber tubing	1
2	Paper/plastic peel pouch	1			

Table D.14 — Analysis: Family member 5

Attribute	Description	Code	Steam penetration resistance (estimated)
General description	Comprises 2-3 medium weight instruments made from stainless steel, plastic, rubber, etc., in a paper/plastic pouch Total weight approximately 500g		e5
Design	Solid Tubing	a1 a5	e1 e5
Material	Stainless steel Plastic, rubber item	b1 b2	e1 e1
Weight	50 g to 250 g	c1 c2	e1
Sterile barrier system and/or packaging system	Paper/plastic peel pouch	d2	e3

D.1.10 Product family

The product family assigned to family member set 5 is PF22. Analysis of the set is illustrated in Table D.15 The assignment of PF22 and steam penetration resistance, e5 is based on the latex tubing. Latex can oxidise in the presence of steam and air and for this reason the operating cycle should be designed accordingly.

Table D.15 — Product family — Classification based on estimates: Family member 5

MD	Attribute																											
	Design (a)								Material (b)		Weight (c)				Sterile barrier system and/or packaging system (d)				Steam penetration resistance (estimated) (e)							
	1	2	3	4	5	6	7	+	1	2	1	2	3	4	1	2	3	4	1	2	3	4	5	6	7	+
22	x				x				x	x	x	x				x					x		x			

D.1.11 Master product

Family member 6 is identified as the master product for the general instruments processing category and is as follows (see Tables D.16 and D.17).

— The design of items in the set comprise pin joints, box locks, metal bowls, tubing and cotton fabric. The greatest challenge is from the set of instruments that are contained in a paper/plastic peel pouch and a dedicated reusable container. Classification is a7 and the estimated steam penetration resistance is e7.

— The material used is stainless steel and cotton. Classification is b2.

— The weight of the Items in the set range between 50 g and 1.000 g and the total weight is 22.000 g. Classification is c3.

— The sterile barrier system is a rigid reusable container. Classification is d3 and the steam penetration resistance is e3.

Table D.16 — Content: Family member 6 (master product)

Item	Description	No	Item	Description	No
1	Forceps	59	10	Basin medium	1
2	Towel clip	8	11	Basin small	1
3	Single tooth tenaculum str	2	12	Iodine cup	1
4	Needle holder	6	13	Medicine cup	1
5	Scissors	6	14	Gauze sponge 4x4	12
6	Knife handle	4	15	Tubing	1
7	Tissue forceps	11	16	Paper/plastic peel pouch 5 x 9	1
8	Surgical towel	3	17	Tray with lid	1
9	Cotton balls	12	18	Rigid reusable sterilization container	1

Table D.17 — Analysis — Family member set 6: Master product

Attribute	Description	Code	Steam penetration resistance (estimated)
General description	Comprises a collection of medium to heavy weight instruments made from stainless steel, arranged on a surgical towel in a perforated metal basket inside a rigid reusable sterilization container. Total weight approximately 22.000 g		e7
Design	Solid Perforated tray Pouch with tissue forceps in micro instrument tray sealed inside metal sterilization container Basin sets Cotton balls Tubing	a1 a1 a7 a3 a4 a5	e1 e3 e7 e3 e3 e5
Material	Stainless steel Cotton fabric towel Cotton balls Plastic tray Paper/plastic peel pouch Latex tubing	b1 b2 b2 b2 b2 b2	e1 e3 e3 e1 e3 e5
Weight	50g to 1.000 g	c1 c2 c3	e1 e1 e1
Sterile barrier system and/or packaging system	Reusable metal sterilization container	d3	e3

D.1.12 Product family

The product family assigned to family member set 6 is PF29. Analysis of the set is illustrated in Table D.18. The assignment of PF29 and steam penetration resistance e7 is based on the instruments contained in a paper/plastic peel pouch placed inside a rigid reusable sterilization container. Family member 6 is the highest weight of the processing category and contains all the items identified in the other family members as the most difficult to sterilize. Family member 6 is identified master product for the general instrument category.

Table D.18 — Product family — Classification based on estimates — Master product: Family member set 6

MD	Attribute																									
PF	Design (a)								Material (b)		Weight (c)				Sterile barrier system and/or packaging system (d)				(e)							
	1	2	3	4	5	6	7	+	1	2	1	2	3	4	1	2	3	4	1	2	3	4	5	6	7	+
29						x	x		x	x	x	x	x				x								x	

D.2 Implant sets and complex orthopaedic sets

The two processing categories are illustrated in Figure D.2 and Figure D.3 respectively. Each category contains four family members from which a master product is selected. The choice is based on the criteria discussed in D.1.12. Tables D.19 to D.22 show the assessment in accordance with Clause 4 for the implant sets. Tables D.23 to D.26 show the assessment for the complex orthopaedic sets.

Key
1 family member 1
2 family member 2
3 family member 3
4 family member 4 — master product

Figure D.2 — Processing category: Implant sets

Table D.19 — Assessment — Family member 1: Tibial plates

Attribute	Description	Code	Steam penetration resistance (estimated)
General description	Comprises a collection light weight implantable plates made from stainless steel or titanium, inside a metal tray with lid wrapped with single use 2 ply wrappers Total weight approximately 2.000g		e4
Design	Solid Perforated tray Towel under and over container	a1 a1 a4	e1 e3 e4
Material	Stainless steel Cotton fabric towel	b1 b2	e1 e3
Weight	50g – 150g	c1 c2	e1 e1
Sterile barrier system and/or packaging system	Metal tray with lid Single use 2 ply wrappers	d3	e4

Table D.20 — Assessment — Family member 2: Cannulated screw set

Attribute	Description	Code	Steam penetration resistance (estimated)
General description	Comprises a collection of light cannulated orthopaedic screws made from stainless steel or titanium arranged in a custom screw tray with lid with a towel over and under the tray with lid, wrapped in single use 2 ply wrappers. Total weight approximately 3.000g		e7
Design	Solid, hollow (less than 1 depth/diameter ratio) Perforated tray Mated surfaces	a1 a1 a7	e1 e3 e7
Material	Stainless steel/titanium Cotton fabric towel	b1 b2	e1 e3
Weight	Average 25g	c1	e1
Sterile barrier system and/or packaging system	Metal container Surgical towels Single use 2 ply wrapper	d3 d3 d3	e4 e4 e3

Table D.21 — Assessment — Family member 3: Bone screw and instrument set

Attribute	Description	Code	Steam penetration resistance (estimated)
General description	Comprises a collection of light to medium weight instruments made from stainless steel, and small orthopaedic screws arranged inside a custom tray with lid with a towel over and under the tray with lid and wrapped with a single use 2 ply wrapper. Total weight approximately 3.500 g		e7
Design	Solid Perforated tray Mated surfaces	a1 a1 a7	e1 e3 e7
Material	Stainless steel Cotton fabric towel	b1 b2	e1 e3
Weight	50 g to 250 g	c1 c2	e1
Sterile barrier system and/or packaging system	Metal tray with lid Surgical towels Single use 2 ply wrapper	d3 d3 d3	e4 e4 e3

Table D.22 — Assessment — Family member 4 — Master product: Fragment instruments, plates and screws set

Attribute	Description	Code	Steam penetration resistance (estimated)
General description	Comprises a collection of medium to heavy weight instruments made from stainless steel, arranged on a surgical towel in a perforated metal tray inside a tray with lid wrapped with a single use 2 ply wrapper. Total weight approximately 4.500 g		e7
Design	Solid Perforated tray Mated surfaces	a1 a1 a7	e1 e3 e7
Material	Stainless steel Cotton fabric towel	b1 b2	e1 e3
Weight	50 g to 250 g	c1 c2	e1 e1
Sterile barrier system and/or packaging system	Metal tray with lid Surgical towels Single use 2 ply wrapper	d3 d3 d3	e4 e4 e3

Key

1 family member 1
2 family member 2
3 family member 3
4 family member 4 —- master product

Figure D.3 — Processing category – complex orthopaedic sets

Table D.23 — Assessment — Family member 1: ACL Instrument set

Attribute	Description	Code	Steam penetration resistance (estimated)
General description	Comprises a collection of medium to heavy weight instruments made from stainless steel, plastic and ceramics arranged in a custom poly-carbonate tray inside an aluminium tray with a lid wrapped with a single use 2 ply wrapper. Total weight approximately 3.200g		e5
Design	Solid Perforated tray Layered tray Moving parts	a1 a1 a5 a5	e1 e3 e5 e4
Material	Stainless steel Polycarbonate Ceramics Cotton fabric towel	b1 b2 b2 b2	e1 e3 e1 e3
Weight	50 g to 500 g	c1 c2	e1 e1
Sterile barrier system and/or packaging system	Single use 2 ply wrapper	d3	e3

Table D.24 — Assessment — Family member 2: Revision reamers

Attribute	Description	Code	Steam penetration resistance (estimated)
General description	Comprises a collection of medium to heavy weight instruments made from stainless steel, plastic and ceramics arranged in a custom poly-carbonate tray inside an aluminium tray with a lid wrapped in a single use 2 ply wrapper. Total weight approximately 6.000g		e5
Design	Solid Perforated tray Layered tray Moving parts	a1 a1 a5 a5	e1 e3 e5 e4
Material	Stainless steel Polycarbonate Ceramics Cotton fabric towel	b1 b2 b2 b2	e1 e3 e1 e3
Weight	50 g to 1.000 g	c1 c2 c3	e1 e3 e3
Sterile barrier system and/or packaging system	Single use 2 ply wrapper	d3	e4

Table D.25 — Assessment — Family member 3: Cup screw instrument set

Attribute	Description	Code	Steam penetration resistance (estimated)
General description	Comprises a collection of medium to heavy weight instruments made from stainless steel, plastic and ceramics arranged in a custom poly-carbonate tray inside an aluminium tray with a lid wrapped in a single use 2 ply wrapper. Total weight approximately 4.000g		e5
Design	Solid Perforated tray Moving parts	a1 a1 a5	e1 e3 e4
Material	Stainless steel Polycarbonate Ceramics Cotton fabric towel	b1 b2 b2 b2	e1 e3 e1 e3
Weight	50 g to 600 g	c1 c2 c3	e1 e3 e3
Sterile barrier system and/or packaging system	single use 2 ply wrapper	d3	e4

Table D.26 — Assessment — Family member 4 — Master product: Hip core instrument set

Attribute	Description	Code	Steam penetration resistance (estimated)
General description	Comprises a collection of medium to heavy weight instruments made from stainless steel, plastic and ceramics arranged in a custom poly-carbonate tray inside an aluminium tray with a lid wrapped with a single use 2 ply wrapper. Total weight approximately 9.000 g		e5
Design	Solid Perforated tray Layered tray Moving parts	a1 a1 a5 a5	e1 e3 e5 e4
Material	Stainless steel Polycarbonate Ceramics Cotton fabric towel	b1 b2 b2 b2	e1 e3 e1 e3
Weight	50 g to 1.000 g	c1 c2 c3	e1 e3 e3
Sterile barrier system and/or packaging system	Single use 2 ply wrapper	d3	e4

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